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CRAIG, PAULA L

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/582,214 | Applicant(s) NEGRIER ET AL. | |
| | Examiner PAULA L. CRAIG | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. The objections to the specification, drawings, and Claim 14 are withdrawn in light of Applicant's amendment filed February 5, 2009. The rejections of Claims 2-3, 5-8, 10-14, and 15-20 under 35 USC 112, second paragraph, are withdrawn in light of Applicant's amendment filed February 5, 2009. As to the rejections under 35 USC 102 and 103, Applicant's arguments filed February 5, 2009 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 21 requires that the groove has a uniform cross sectional area in an axial direction of the groove, which the specification

Art Unit: 3761

as filed does not expressly teach. Claim 22 requires that the groove has a constant depth and a constant width perpendicular to the axial direction of the groove, which the specification as filed does not expressly teach. Claim 23 requires graduations perpendicular to the groove which extend from the surface of the applicator stick in a depth direction of the groove, which the specification as filed does not expressly teach. Claim 25 requires that each compartment in the series of compartments has a successively larger volume. The specification as filed does not expressly teach that each compartment in the series of compartments has a successively larger volume.

5. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 25 requires that each compartment has a successively larger volume. Claim 25 is dependent on Claims 24, 23, 22, and 1; none of these claims requires that the series includes more than a single compartment (note that Claim 14 makes it clear that Claim 1 requires no more than a single compartment). It is not clear to the Examiner whether or not Claim 25 requires that the series include multiple compartments.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3761

7. Claims 1-2, 4, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,486,194 to Ferrara.

8. For Claim 1, Ferrara teaches a metering device for a product intended to be applied to skin, in particular a pharmaceutical or cosmetic composition (Abstract, Figs. 1-8, col. 1, lines 5-11, col. 2, lines 41-53, Claim 1). An applicator stick with a longitudinal groove is divided into a series of compartments (applicator stick includes chambers 24 and 56 and at least the center section of support members 12 and 38; compartments include channels 40, container 60, and the spaces between and around lines 28 and raised members 34, 36 and 36a; Abstract, Figs. 1-8, col. 2, line 41 to col. 3, line 34, Claim 1). Ferrara teaches the groove accommodating a quantity of composition corresponding to a defined surface area of skin to be treated, the quantity of composition being defined by the series of compartments (Abstract, Figs. 1-8, col. 1, lines 5-11 and 42-46, col. 1, line 59 to col. 2, line 8, col. 2, line 52 to col. 3, line 2, Claim 1). The groove defines an uncovered depression in a top surface of the applicator stick such that an entirety of the groove is exposed opposite the depression (Figs. 1-8, col. 1, lines 5-30, col. 1, line 59 to col. 2, line 11, col. 2, lines 41-51, Claim 1).

9. For Claim 2, Ferrara teaches the applicator stick being fitted with graduations which, from one end of the groove correspond to the start of a first compartment, wherein the graduations define boundaries of the series of compartments such that the graduations define the quantity of composition in each of the series of compartments of the groove (graduations include numerals 30, lines 28, and raised members 34, 36, and 36a; Abstract, Figs. 1-6, col. 2, lines 2-8, col. 2, line 52 to col. 3, line 29, Claim 1).

Art Unit: 3761

10. For Claim 4, Ferrara teaches graduations of the applicator stick being a graduated scale, protuberances, or notches (Figs. 1-6, col. 1, line 67 to col. 2, line 8, col. 2, line 52 to col. 3, line 20, Claim 1).

11. For Claim 27, Ferrara teaches the applicator stick including a lower surface on an opposite side of the applicator stick with respect to the top surface, and the groove defining a bulge on the lower surface of the applicator stick (Figs. 2, 4-5, and 7; col. 2, line 52 to col. 3, line 36; note bulge in top support member 12 opposite medicament 26 in Fig. 2). The bulge is fully capable of inclining the metering device when placed on a flat surface (Figs. 2, 4-5, and 7; col. 2, line 52 to col. 3, line 36).

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 532,359 to Bradley.

13. For Claim 1, Bradley teaches a metering device for a product fully capable of being applied to skin, in particular a pharmaceutical composition (Figs. 1-5, page 1, lines 10-67). An applicator stick C with a longitudinal groove is divided into a series of compartments (longitudinal grooves include spiral grooves, straight grooves, and rows of indentations; Figs. 1-5, page 1, lines 10-67, Claims 1-3). The groove is fully capable of accommodating a quantity of composition corresponding to a defined surface area of skin to be treated (Figs. 1-5, page 1, lines 10-67). The quantity of composition is defined by the series of compartments (Figs. 1-5, page 1, lines 10-67). The groove defines an uncovered depression in a top surface of the applicator stick such that an

Art Unit: 3761

entirety of the groove is exposed opposite the depression (Figs. 15, page 1, lines 10-67).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 3, 5-8, 14-19, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrara.

16. For Claims 3 and 14, Ferrara teaches all the limitations of Claims 1 and 2, as described above in paragraphs 8 and 9 respectively. Ferrara teaches the groove including first and second compartments (compartments are divided by lines 28 and by raised members 34, 36, and 36a; Figs. 1 and 3-6, col. 2, line 57 to col. 3, line 14). Figs. 1, 3, and 6 suggest third and fourth compartments (each of Figs. 1 and 3 shows about nine lines 28 dividing the compartments; Fig. 4 shows thirteen raised members 34, 36,

Art Unit: 3761

and 36a; Fig. 6 shows about eight lines; col. 1, line 67 to col. 2, line 8, col. 2, line 52 to col. 3, line 29). Ferrara does not expressly teach third and fourth compartments. In light of the multiple divisions shown in Ferrara's figures, it would have been obvious to one of ordinary skill in the art to modify Ferrara to include third and fourth compartments.

17. For Claims 5-8 and 16-19, Ferrara teaches each compartment of the device containing a suitable quantity of the composition (Figs. 1-8, col. 1, line 5 to col. 4, line 3, Claim 1). Ferrara does not expressly teach the first, second, third, or fourth compartment being able to contain a quantity of composition corresponding to an area of a total surface of a body. The quantity of the composition dispensed by the device is a result effective variable, since it affects the dosage delivered. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney*, 205USPQ 215 (CCPA 1980). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ferrara to include each compartment being able to contain a suitable quantity of the composition.

18. For Claim 15, Ferrara teaches graduations of the applicator stick being a graduated scale, protuberances, or notches (Figs. 1-6, col. 1, line 67 to col. 2, line 8, col. 2, line 52 to col. 3, line 20, Claim 1).

19. For Claim 21, Ferrara teaches a groove (groove includes area enclosed by side wall 22, grooves 40, and container 60; Figs. 1-8). Figs. 1-8 of Ferrara suggest that the grooves have a uniform cross sectional area in an axial direction of the groove (note that Figs. 1, 3, 6, and 8 appear to show grooves which are generally rectangular).

Art Unit: 3761

Ferrara does not expressly teach the groove having a uniform cross sectional area in an axial direction of the groove. In light of Ferrara's figures, it would have been obvious to one of ordinary skill in the art to modify Ferrara to include a groove having a uniform cross sectional area in an axial direction of the groove.

20. For Claim 22, Ferrara teaches a groove (groove includes area enclosed by side wall 22, grooves 40, and container 60; Figs. 1-8). Figs. 1-8 of Ferrara suggest that the grooves have a constant depth and a constant width perpendicular to the axial direction of the groove. Ferrara does not expressly teach the groove having a constant depth and a constant width perpendicular to the axial direction of the groove. In light of Ferrara's figures, it would have been obvious to one of ordinary skill in the art to modify Ferrara to include a groove having a constant depth and a constant width perpendicular to the axial direction of the groove.

21. For Claim 23, Ferrara teaches graduations perpendicular to the groove (lines 28 are perpendicular to the groove; Figs. 1-3, col. 2, lines 52-64). Ferrara teaches graduations extending from the surface of the applicator stick in a depth direction of the groove (Figs. 4 and 7, col. 2, lines 2-11, col. 3, lines 7-14, Claim 1). Ferrara does not expressly teach the graduations perpendicular to the groove extending from the surface of the applicator stick in a depth direction of the groove. In light of Ferrara's teaching of graduations perpendicular to the groove and of graduations extending from the surface of the applicator stick in a depth direction of the groove, it would have been obvious to one of ordinary skill in the art to modify Ferrara to include the graduations perpendicular

to the groove extending from the surface of the applicator stick in a depth direction of the groove.

22. For Claim 24, Ferrara teaches the graduations dividing the groove into the series of compartments, with a volume of a compartment defined by a length of the compartment in the axial direction (Abstract, Figs. 1-6, col. 1, lines 5-11, col. 2, lines 2-11, col. 2, line 52 to col. 3, line 29, Claim 1).

23. For Claim 25, Figs. 1 and 4 of Ferrara suggest that at least one compartment in the series is larger than the others (Fig. 1 shows the distance between the first graduation and the end wall, and between the last graduation and the end wall, being smaller than the distance between the graduations; Fig. 4 also shows the distance between graduations and the walls being different from the distance between graduations). Ferrara does not expressly teach each compartment in the series of compartments having a successively larger volume. In light of Ferrara's figures, it would have been obvious to one of ordinary skill in the art to modify Ferrara to include at least one compartment having a larger volume than another in the series of compartments.

24. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley.

25. For Claim 26, Bradley teaches the applicator stick including a flared portion and a narrow portion, the narrow portion extending from a first end of the applicator stick to the flared portion in an axial direction of the groove (flared portion includes head c; narrow portion includes the remainder of rod C; Figs. 1 and 3, page 1, lines 33-74). The flared portion extends beyond the groove to a second end of the applicator stick, with

Art Unit: 3761

the flared portion including a greater width than the narrow portion in a transverse direction of the applicator stick, so as to facilitate handling the applicator stick (Figs. 1-5, page 1, lines 33-74). Figs. 1-5 of Bradley suggest that the flared portion is circular. Bradley does not expressly teach the flared portion being circular. In light of Figs. 1-5 of Bradley, it would have been obvious to one of ordinary skill in the art to modify Bradley to include the flared portion being circular.

26. Claims 9-13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrara in view of U.S. Patent No. 6,284,234 to Niemiec et al.

27. For Claims 9 and 20, Ferrara teaches all the limitations of Claims 1 and 3, as described above in paragraphs 8 and 16 respectively. Ferrara teaches application of a composition to the skin using a skin patch (col. 1, lines 5-30, col. 2, lines 41-51, Claim 1). Ferrara does not teach the composition treating psoriasis or being calcitriol.

However, the application of calcitriol to treat psoriasis is well known in the art. Niemiec confirms this and teaches the use of calcitriol to treat psoriasis (col. 13, lines 13-33).

Niemiec teaches that this composition may be applied to the skin in a variety of ways, including application using a skin patch (col. 15, lines 12-26). In light of Ferrara's teaching of application of a composition to the skin using a skin patch, it would have been obvious to one of ordinary skill in the art to modify Ferrara to include the composition being calcitriol used to treat psoriasis, as taught by Niemiec. See MPEP 2115.

Art Unit: 3761

28. For Claims 10-13, Ferrara teaches each compartment of the device containing a suitable quantity of the composition (Figs. 1-8, col. 1, line 5 to col. 4, line 3, Claim 1).

Ferrara does not expressly teach the first, second, third, or fourth compartment being able to contain a quantity of 0.35 g to 0.54 g, 1.08 g to 1.62 g, 2.16 g to 3.20 g. or 3.24 g to 4.86 g. The quantity of the composition dispensed by the device is a result effective variable, since it affects the dosage delivered. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney*, 205USPQ 215 (CCPA 1980). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ferrara to include each compartment being able to contain a suitable quantity of the composition.

Conclusion

29. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3761

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAULA L. CRAIG whose telephone number is (571)272-5964. The examiner can normally be reached on M-F 8:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

/Paula L Craig/
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